Requests for waiver or alteration of the informed consent process may be allowed if the IRB finds that the following criteria are met:

(1) The research involves no more than minimal risk to the subjects;
(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) the research could not practicably be carried out without the waiver or alteration; and
(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

OHRP 45 CFR 46.116(d)

Note: FDA-regulated research is NOT eligible for a waiver or alteration of consent, except for emergency use of a test article FDA 21 CFR 50.23, or planned emergency research FDA 21 CFR 50.24.

An IRB may waive the requirement to document informed consent (waiver of signed consent, e.g. Preamble) if it finds that one of these criteria is met:

OHRP 45 CFR 46.117(c)(1)

For research not subject to FDA regulation, the IRB finds:
That the only record linking the subjects and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

OHRP 45 CFR 46.117(c)(2)

FDA 21 CFR 56.109(c)(1)

For research subject either to OHRP or FDA regulation, the IRB finds:
That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Topics for consideration in determining when parent permission may not be waived or altered:

- Illegal, antisocial, or self-incriminating behavior
- Relationship legally recognized as privileged (lawyers, doctors, clergy)
- Sexual behavior or attitudes
- Mental or psychological problems
- Religious affiliations or beliefs
- Parental political affiliations or beliefs
- Appraisals of other individuals with whom the child has a familial relationship
- FDA-regulated research (unless the emergency use of a test article exception applies)
An investigator may request a waiver of informed consent if the following four criteria are met. The investigator is required to provide protocol specific justification in their IRB application on how the study meets each one of the four criteria below. Stating “not applicable” or just re-stating the criteria is not an acceptable response.

After each statement, add the word “because” and then formulate your justification. Below are some examples that may help you provide justification for your study.

1. **Involves minimal to no risk to the subjects:**

   The study involves minimal to no risk to subjects because...

   - The only known risk to patients is the possible loss of confidentiality, which has been guarded against by… (give the ways in which data will be kept secure e.g. encryptions, limited access personnel, limited access area, password protection, etc.) as described in (section x of the application, and section y of the protocol)

2. **The waiver will not adversely affect the rights and welfare of the subjects:**

   The waiver will not adversely affect the rights and welfare of subjects because...

   - This study is non-interventional and does not affect the subject’s rights for patient care and does not interfere in their welfare. Subject rights and confidentiality will be protected by such measures as (state examples here...)

3. **The research could not practicably be carried out without the waiver or alteration:**

   The research could not practicably be carried out without the waiver or alteration because....

   In order to answer our research question, we must view (# of) medical records for a retrospective data collection, and the waiver is needed because it would be impractical to obtain consent for (x# of) as these subjects...

   - are not seen by research staff on a regular basis, or
   - much time as elapsed since these subjects were last seen locally
   - the hours needed to contact these subjects for consent would exceed the ability of our research staff

4. **Whenever appropriate, the subjects will be provided with additional pertinent information after participation:**

   - This study is non-interventional and thus providing information to patients is not likely. However, if there were information that needed to be provided to the subject we would work with the IRB to approve the correspondence to be provided to the subject.

   OR

   - We are reviewing medical records but are not recording identifiers. We would not be able to link subjects back to the study and therefore would not be able to provide additional information.